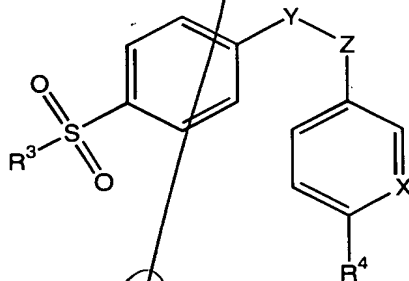


## WHAT IS CLAIMED IS:

1. A process for preparing an oral fast-melt pharmaceutical composition, the process comprising
- (a) a step of wet granulating a selective cyclooxygenase-2 inhibitory drug together with a liquid binding agent comprising a saccharide having high moldability, and
- (b) a step of blending with the drug a saccharide having low moldability, wherein said steps (a) and (b) occur in any order or simultaneously to result in formation of granules, and wherein the process incorporates means to inhibit agglomeration of the drug.
2. The process of Claim 1 wherein said step (b) occurs prior to or simultaneously with said step (a).
3. The process of Claim 1 wherein said wet granulating step comprises fluid bed granulation.
4. The process of Claim 1 wherein the selective cyclooxygenase-2 inhibitory drug is a compound having the formula:



- where R<sup>3</sup> is a methyl or amino group, R<sup>4</sup> is hydrogen or a C<sub>1-4</sub> alkyl or alkoxy group, X is N or CR<sup>5</sup> where R<sup>5</sup> is hydrogen or halogen, and Y and Z are independently carbon or nitrogen atoms defining adjacent atoms of a five- to six-membered ring that is unsubstituted or substituted at one or more positions with oxo, halo, methyl or halomethyl groups.
5. The process of Claim 4 wherein the five- to six-membered ring is selected from cyclopentenone, furanone, methylpyrazole, isoxazole and pyridine rings substituted at no more than one position.

6. The process of Claim 1 wherein the selective cyclooxygenase-2 inhibitory drug is selected from celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.
7. The process of Claim 1 wherein the selective cyclooxygenase-2 inhibitory drug is selected from celecoxib, valdecoxib, rofecoxib and etoricoxib.
8. The process of Claim 1 wherein the selective cyclooxygenase-2 inhibitory drug is celecoxib.
9. The process of Claim 1 wherein the selective cyclooxygenase-2 inhibitory drug is valdecoxib.
10. The process of Claim 1 wherein said saccharide having low moldability is selected from lactose, mannitol, glucose, sucrose and xylitol.
11. The process of Claim 1 wherein said saccharide having low moldability is mannitol of powder grade.
12. The process of Claim 1 wherein said saccharide having high moldability is selected from maltose, maltitol, sorbitol and oligosaccharides having 2 to 6 monosaccharide residues.
13. The process of Claim 1 wherein said saccharide having high moldability is maltose.
14. The process of Claim 1 wherein said means to inhibit agglomeration comprises pre-wetting the drug prior to said step (a).
15. The process of Claim 1 wherein said means to inhibit agglomeration of the drug comprises addition of a wetting agent.
16. The process of Claim 15 wherein the wetting agent is selected from quaternary ammonium compounds, dioctyl sodium sulfosuccinate, polyoxyethylene alkylphenyl ethers, poloxamers, polyoxyethylene fatty acid glycerides and oils, polyoxyethylene alkyl ethers, polyoxyethylene fatty acid esters, polyoxyethylene

sorbitan esters, propylene glycol fatty acid esters, sodium lauryl sulfate, fatty acids and salts thereof, glyceryl fatty acid esters, sorbitan esters, tyloxapol and mixtures thereof.

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- 10 17. The process of Claim 15 wherein the wetting agent is sodium lauryl sulfate.
- 5 18. The process of Claim 15 wherein said wetting agent is added in a total amount of about 0.05% to about 5% by weight of the composition.
19. The process of Claim 15 wherein said wetting agent is added in a total amount of about 0.075% to about 2.5% by weight of the composition.
20. The process of Claim 15 wherein said wetting agent is added in a total amount of about 0.25% to about 1% by weight of the composition.
21. The process of Claim 1 further comprising addition of a glidant.
22. The process of Claim 21 wherein said glidant is silicon dioxide.
23. The process of Claim 21 wherein said glidant is added in a total amount of about 0.05% to about 5% by weight of the composition.
- 15 24. The process of Claim 21 wherein said glidant is added in a total amount of about 0.1% to about 2% by weight of the composition.
25. The process of Claim 21 wherein said glidant is added in a total amount of about 0.25% to about 1% by weight of the composition.
- 20 26. The process of Claim 1 wherein said selective cyclooxygenase-2 inhibitory drug is present in a total amount of about 1% to about 75% by weight of the composition.
27. The process of Claim 1 wherein said selective cyclooxygenase-2 inhibitory drug is present in a total amount of about 15% to about 75% by weight of the composition.
- 25 28. The process of Claim 1 wherein said selective cyclooxygenase-2 inhibitory drug is present in a total amount of about 30% to about 75% by weight of the composition.
29. The process of Claim 1 wherein said selective cyclooxygenase-2 inhibitory drug
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is present in a total amount of about 45% to about 75% by weight of the composition.

30. The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 10% by weight of the composition.

31. The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 7.5% by weight of the composition.

32. The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 5% by weight of the composition.

33. The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 10% to about 90% by weight of the composition.

34. The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 15% to about 60% by weight of the composition.

35. The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 25% to about 50% by weight of the composition.

36. The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 2:100 to about 20:100.

37. The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 10:100.

38. The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 7.5:100.

39. The process of Claim 1, further comprising

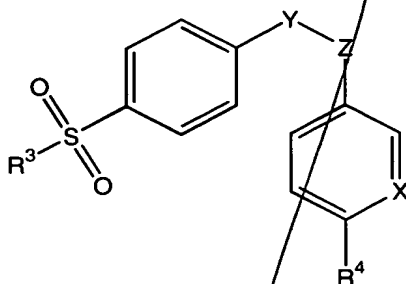
- (c) a step of blending said granules with at least one of a lubricant, a sweetening agent and a flavoring agent to form a tableting blend, and
- (d) a step of compressing the tableting blend to form oral fast-melt tablets.
40. The process of Claim 39 wherein parameters are set in said compressing step (d) to provide tablets having a hardness of about 1 to about 10 kp.
41. An oral fast-melt pharmaceutical composition prepared by the process of Claim 1.
42. An oral fast-melt composition comprising a selective cyclooxygenase-2 inhibitory drug dispersed in a matrix comprising a saccharide of low moldability and a saccharide of high moldability.
43. The composition of Claim 42 further comprising a wetting agent.
44. The composition of Claim 43 wherein said wetting agent is selected from quaternary ammonium compounds, dioctyl sodium sulfosuccinate, polyoxyethylene alkylphenyl ethers, poloxamers, polyoxyethylene fatty acid glycerides and oils, polyoxyethylene alkyl ethers, polyoxyethylene fatty acid esters, polyoxyethylene sorbitan esters, propylene glycol fatty acid esters, sodium lauryl sulfate, fatty acids and salts thereof, glyceryl fatty acid esters, sorbitan esters, tyloxapol and mixtures thereof.
45. The composition of Claim 43 wherein said wetting agent is sodium lauryl sulfate.
46. The composition of Claim 43 wherein said wetting agent is present in an amount of about 0.05% to about 5% by weight of the composition.
47. The composition of Claim 43 wherein said wetting agent is present in an amount of about 0.075% to about 2.5% by weight of the composition.
48. The composition of Claim 43 wherein said wetting agent is present in an amount of about 0.25% to about 1% by weight of the composition.
49. The composition of Claim 42 further comprising a glidant.
50. The composition of Claim 49 wherein said glidant is silicon dioxide.
51. The composition of Claim 49 wherein said glidant is present in an amount of

about 0.05% to about 5%.

52. The composition of Claim 49 wherein said glidant is present in an amount of about 0.1% to about 2%.

53. The composition of Claim 49 wherein said glidant is present in an amount of about 0.25% to about 1%.

54. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is a compound having the formula:



where  $R^3$  is a methyl or amino group,  $R^4$  is hydrogen or a  $C_{1-4}$  alkyl or alkoxy group,  $X$  is  $N$  or  $CR^5$  where  $R^5$  is hydrogen or halogen, and  $Y$  and  $Z$  are independently carbon or nitrogen atoms defining adjacent atoms of a five- to six-membered ring that is unsubstituted or substituted at one or more positions with oxo, halo, methyl or halomethyl groups; or a prodrug of such a compound.

55. The composition of Claim 54 wherein the five- to six-membered ring is selected from cyclopentenone, furanone, methylpyrazole, isoxazole and pyridine rings substituted at no more than one position.

56. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is selected from celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.

57. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is selected from celecoxib, valdecoxib, rofecoxib and etoricoxib.

58. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory

drug is celecoxib.

59. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is valdecoxib.

5 60. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is present in an amount of about 1% to about 75% by weight of the composition.

61. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is present in an amount of about 15% to about 75% by weight of the composition.

10 62. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is present in an amount of about 30% to about 75% by weight of the composition.

15 63. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is present in an amount of about 45% to about 75% by weight of the composition.

64. The composition of Claim 42 wherein said saccharide having low moldability is selected from lactose, mannitol, glucose, sucrose and xylitol.

65. The composition of Claim 42 wherein said saccharide having low moldability is mannitol of powder grade.

20 66. The composition of Claim 42 wherein said saccharide having low moldability is present in an amount of about 10% to about 90% by weight of the composition.

67. The composition of Claim 42 wherein said saccharide having low moldability is present in an amount of about 15% to about 60% by weight of the composition.

25 68. The composition of Claim 42 wherein said saccharide having low moldability is present in an amount of about 25% to about 50% by weight of the composition.

69. The composition of Claim 42 wherein said saccharide having high moldability is selected from maltose, maltitol, sorbitol and oligosaccharides having 2 to 6 monosaccharide residues.

70. The composition of Claim 42 wherein said saccharide having high moldability is

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maltose.

71. The composition of Claim 42 wherein said saccharide having high moldability is present in an amount of about 1% to about 10% by weight of the composition.
72. The composition of Claim 42 wherein said saccharide having high moldability is present in an amount of about 1% to about 7.5% by weight of the composition.
73. The composition of Claim 42 wherein said saccharide having high moldability is present in an amount of about 1% to about 5% by weight of the composition.
74. The composition of Claim 42 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 2:100 to about 20:100.
75. The composition of Claim 42 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 10:100.
76. The composition of Claim 42 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 7.5:100.
77. The composition of Claim 42 that is a tablet.
78. The tablet of Claim 77 that disintegrates within about 30 to about 300 seconds in a standard *in vitro* disintegration assay.
79. The tablet of Claim 77 that disintegrates within about 30 to about 200 seconds in a standard *in vitro* disintegration assay.
80. The tablet of Claim 77 that disintegrates within about 30 to about 150 seconds in a standard *in vitro* disintegration assay.
81. The tablet of Claim 77 that disintegrates within about 5 to about 60 seconds after placement in the oral cavity of a subject.
82. The tablet of Claim 77 that disintegrates within about 5 to about 30 seconds after placement in the oral cavity of a subject.
83. The tablet of Claim 77 that disintegrates within about 5 to about 25 seconds after



placement in the oral cavity of a subject.

84. ✓ A process for preparing an oral fast-melt pharmaceutical composition, the process comprising

(a) a step of wet granulating a selective cyclooxygenase-2 inhibitory drug together with a liquid binding agent comprising a saccharide having high moldability, and

(b) a step of blending with the drug a saccharide having low moldability and a glidant,

wherein said steps (a) and (b) occur in any order or simultaneously to result in formation of granules.

85. An oral fast-melt pharmaceutical composition prepared by the process of Claim 84.

86. A method of treating a medical condition or disorder in a mammalian subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering to the subject a composition of Claim 42.

87. The method of Claim 86 wherein said mammalian subject is a human subject.

88. The method of Claim 87 that further comprises combination therapy with one or more drugs selected from opioids and other analgesics.

89. The method of Claim 87 that further comprises combination therapy with an opioid compound selected from codeine, meperidine, morphine and derivatives thereof.